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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/658,100	09/09/2003	Knut Rudi	11630/US/2	9968

30873 7590 04/03/2006

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EXAMINER	
SWITZER, JULIET CAROLINE	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 04/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/658,100	RUDI ET AL.	
	Examiner	Art Unit	
	Juliet C. Switzer	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 September 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/646,847.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The preliminary amendment canceling claims 1-20 and adding new claims 22-40 has been entered. Claims 21-40 are under prosecution herein.

2. The IDS filed 10/23/03 has been considered. A signed copy of the 1449 is enclosed with this office action.

3. The title of the invention is not descriptive of the claimed invention, since the title of the application refers to methods and the pending claims are all drawn to kits. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 21-30 and 32-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Pastinen et al. (Clinical Chemistry, 42:9, 1391-1397, 1996, as cited in IDS).

The term "kit," though mentioned in the specification, is not defined in the specification. In this rejection, the word is being broadly interpreted to include a collection of reagents.

Pastinen et al. teach a collection of reagents which comprises an oligonucleotide probe (p. 1392; referred to therein as "detection primers"), a means for selective labeling of the probe (p. 1392, including, DNA polymerase, fluoresin labeled ddNTP, and unlabeled dNTP), and a nucleotide sequence complementary to the oligonucleotide probe (p. 1391, biotynlated single

stranded amplification product bound to solid support). Thus, Pastinen et al. teach a collection of reagents that meet the limitations of claim 21.

Regarding claim 22, the nucleotide sequence of the capture probe is fully complementary to some of the detection primers (Table 1, and p. 1392, 1st column). Regarding claim 23, the oligonucleotide probes include some probes that are 20 to 30 nucleotides in length (for example DQA1:34, see Table 1).

Regarding claim 24, the means for selectively labeling includes polymerase which provides for incorporation of a labeled nucleotide (p. 1393, 1st column). Regarding claim 25, the means for selective labeling includes a labeled nucleotide, and regarding claim 26, the labeled nucleotide is a dideoxynucleotide, and regarding claims 27 and 28, the means further includes one labeled dideoxynucleotide and three unlabelled dideoxynucleotides (p. 1393, 1st column).

Regarding claim 29, Pastinen teaches a primer that has a degenerate oligonucleotide at the 3' end, depending on the target molecule and the version of the primer, then, this primer is designed with one or more mismatches at the 3'end to non-target sequences (see primer DQA1:34, for example). Further, all of the primers taught by Pastinen et al. are designed to be complementary to target sequences, and therefore would have mismatches throughout relative to non-target sequences.

Regarding claim 30, the sequence complementary to the oligonucleotide probe (where the a "detection primer" is interpreted as being the "oligonucleotide probe") is immobilized on a solid support.

Regarding claim 32, the set of reagents taught by Pastinen et al. includes a means to amplify the target nucleic acid sequence, including primers, polymerase and dNTP (p. 1392, for example).

Regarding claim 33, Pastinen et al. teach DNA preparations which comprise heterozygous samples for amplification, and where one allele is considered the "target nucleic acid" the other allele is considered "a competitor nucleic acid for coamplification" (p. 1391, and evidenced by Figure 3 showing heterozygous samples). Regarding claim 34, thus, the competitor inherently comprises a recognition sequence complementary to a competitor oligonucleotide probe (which is a "detection primer"), and regarding claim 35, these competitor oligonucleotide probes are within the set of reagents taught by Pastinen et al., and regarding claim 36, they are capable of being selectively labeled. Regarding claim 37, Pastinen et al. teach a means for detecting labeled probes, including a polyacrylamide gel, and an automated sequencer (p. 1393). Regarding claim 38, the sequences which are complementary to the oligonucleotide probe are immobilized in the solid support in discrete, predetermined positions (see Figure 1 showing the comb positions).

Regarding claim 39, Pastinen et al. teach the analysis of human HLA alleles which are characteristic of humans, and regarding claim 40, Pastinen et al. teach a plurality of different probes, each being capable of binding different target sequences (at different polymorphic HLA positions) and each polymorphic position (target sequence) is characteristic of a particular organism- that is humans.

6. Claims 21-22, 24-25, and 29-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Ugozzoli et al. (GATA 9(4), 107-112, 1992, as cited in IDS).

The term "kit," though mentioned in the specification, is not defined in the specification. In this rejection, the word is being broadly interpreted to include a collection of reagents.

Ugozzoli et al. teach a collection of reagents which comprises an oligonucleotide probe (p. 109, Figure 1; referred to therein as "AS-PE primer"), a means for selective labeling of the probe (p. 109, including, DNA polymerase, α-^{32}P-labeled nucleotide), and a nucleotide sequence complementary to the oligonucleotide probe (p. 108, figure 1, referred to as "the immobilized oligonuceltides"). Thus, Ugozzoli et al. teach a collection of reagents that meet the limitations of claim 21.

Regarding claim 22, the nucleotide sequence of the capture probe is fully complementary to the of the detection primers, albeit to only a portion of the oligonucleotide probe (Figure 1, for example).

Regarding claim 24, the means for selectively labeling includes polymerase which provides for incorporation of a labeled nucleotide (p. 109, 1st column). Regarding claim 25, the means for selective labeling includes a labeled nucleotide (p. 109, 1st column).

Regarding claim 29, Ugozzoli teaches the primers have a nucleotide sequence at the 3' end that does not hybridize to the target sequence (Figure 1). Further, all of the primers taught by Ugozzoli et al. are designed to be complementary to target sequences, and therefore would have mismatches throughout relative to non-target sequences.

Regarding claim 30, the sequence complementary to the oligonucleotide probe (where the a "detection primer" is interpreted as being the "oligonucleotide probe") is immobilized on a solid support (Figure 1). Regarding claim 31, the solid support is a membrane strip (p. 108 and Figure 1)

Regarding claim 32, the set of reagents taught by Ugozzoli et al. includes a means to amplify the target nucleic acid sequence, including primers, polymerase and dNTP (p. 108-109).

Regarding claim 33, Ugozzoli et al. teach DNA preparations which comprise heterozygous samples for amplification, and where one allele is considered the "target nucleic acid" the other allele is considered "a competitor nucleic acid for coamplification" (p. 108, and evidenced by Figure 2 showing heterozygous samples). Regarding claim 34, thus, the competitor inherently comprises a recognition sequence complementary to a competitor oligonucleotide probe (which is a "AS-PE primer"), and regarding claim 35, these competitor oligonucleotide probes are within the set of reagents taught by Ugozzoli et al., and regarding claim 36, they are capable of being selectively labeled. Regarding claim 37, Ugozzoli et al. teach a means for detecting labeled probes, including a Kodak film and polyacrylamide gel (p. 109). Regarding claim 38, the sequences which are complementary to the oligonucleotide probe are immobilized in the solid support in discrete, predetermined positions (see Figure 2 showing the dot blot positions).

Regarding claim 39, Ugozzoli et al. teach the analysis of human TYR alleles which are characteristic of humans, and regarding claim 40, Ugozzoli et al. teach a plurality of different probes, each being capable of binding different target sequences (at different TYR alleles) and each polymorphic position (target sequence) is characteristic of a particular organism- that is humans (Figure 1).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 21-30 and 32-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pastinen et al. in view of Ahern (The Scientist, Vol. 9, Number 15, p. 20, 1995; Print out from internet provided, pages numbered 1-5, printed 12/22/98).

The specification does not define what is meant by "kit." This rejection is written in view of a narrower interpretation of "kit" wherein the recitation of the word "kit" that the claimed reagents are packaged in a single packaging, for example a box. Pastinen et al. teaches reagents which meet the limitations of those set forth in the claims.

Pastinen et al. teach a collection of reagents which comprises an oligonucleotide probe (p. 1392; referred to therein as "detection primers"), a means for selective labeling of the probe (p. 1392, including, DNA polymerase, fluoresin labeled ddNTP, and unlabeled dNTP), and a nucleotide sequence complementary to the oligonucleotide probe (p. 1391, biotynlated single stranded amplification product bound to solid support). Thus, Pastinen et al. teach a collection of reagents that meet the limitations of claim 21.

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Regarding claim 30, the sequence complementary to the oligonucleotide probe (where the a "detection primer" is interpreted as being the "oligonucleotide probe") is immobilized on a solid support.

Regarding claim 32, the set of reagents taught by Pastinen et al. includes a means to amplify the target nucleic acid sequence, including primers, polymerase and dNTP (p. 1392, for example).

Regarding claim 33, Pastinen et al. teach DNA preparations which comprise heterozygous samples for amplification, and where one allele is considered the "target nucleic acid" the other allele is considered "a competitor nucleic acid for coamplification" (p. 1391, and evidenced by Figure 3 showing heterozygous samples). Regarding claim 34, thus, the competitor inherently comprises a recognition sequence complementary to a competitor oligonucleotide probe (which is a "detection primer"), and regarding claim 35, these competitor oligonucleotide probes are within the set of reagents taught by Pastinen et al., and regarding claim 36, they are capable of being selectively labeled. Regarding claim 37, Pastinen et al. teach a means for detecting labeled probes, including a polyacrylamide gel, and an automated sequencer (p. 1393). Regarding claim 38, the sequences which are complementary to the oligonucleotide probe are immobilized in the solid support in discrete, predetermined positions (see Figure 1 showing the comb positions).

Regarding claim 39, Pastinen et al. teach the analysis of human HLA alleles which are characteristic of humans, and regarding claim 40, Pastinen et al. teach a plurality of different probes, each being capable of binding different target sequences (at different polymorphic HLA positions) and each polymorphic position (target sequence) is characteristic of a particular organism- that is humans.

Pastinen et al. do not particularly teach this set of reagents packaged together. At the time the invention was made, however, the benefits of providing kits to a practitioner were widely known. For example, Ahern provides a detailed discussion throughout of the advantages of the ready-made purchase of biochemical kits, including that purchasing reagents ready made saves the practitioner time and money. Thus, at the time the invention was made, it would have been

prima facie obvious to one of ordinary skill in the art to have packaged the reagents taught by Pastinen et al. into a kit for sale to scientists. One would have been motivated to do so by the teachings of Ahern, who states "The large selection of prepared biochemicals and kits has certainly made life easier for countless researchers" and one would have been motivated to produce such kits to help researchers and to provide a valuable product which could be sold for profit.

10. Claims 21-22, 24-25, and 29-40 21-22, 24-25, and 29-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ugozzoli et al. in view of Ahern.

The specification does not define what is meant by "kit." This rejection is written in view of a narrower interpretation of "kit" wherein the recitation of the word "kit" that the claimed reagents are packaged in a single packaging, for example a box. Ugozzoli et al. teach reagents which meet the limitations of those set forth in the claims.

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Claim Rejections - 35 USC § 112

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claim 30 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 30, the recitation "the labeled oligonucleotide" lacks proper antecedent basis because there is no labeled oligonucleotide previously recited in the claim.

Conclusion

13. No claim is allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C Switzer whose telephone number is (571) 272-0753. The examiner can normally be reached on Monday, Tuesday, or Thursday, from 9:00 AM until 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached by calling (571) 272-0735.

The fax phone numbers for the organization where this application or proceeding is assigned are (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-0507.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is

(866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Juliet C. Switzer
Primary Examiner
Art Unit 1634

March 30, 2006